

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

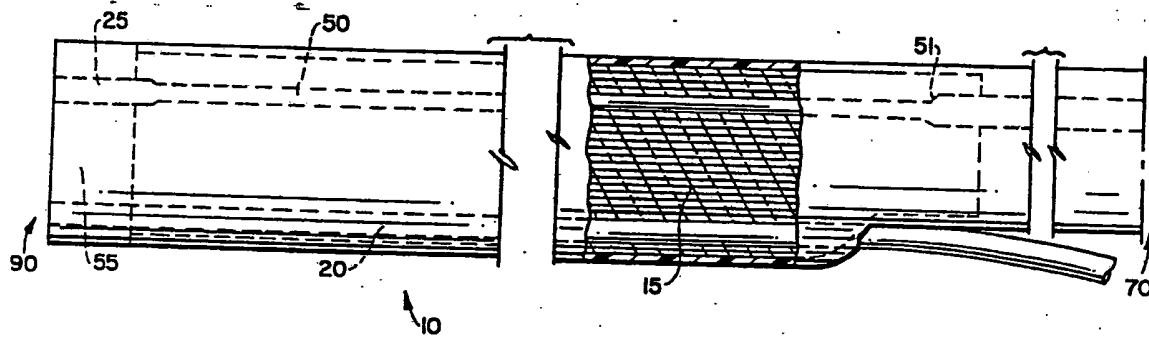


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :	A1	(11) International Publication Number: WO 93/18818
A61M 37/00		(43) International Publication Date: 30 September 1993 (30.09.93)

(21) International Application Number: PCT/US93/02225	(74) Agents: LAZAR, Dale, S. et al.; Cushman, Darby & Cushman, 1100 New York Avenue, N.W., Washington, DC 20005 (US).
(22) International Filing Date: 17 March 1993 (17.03.93)	
(30) Priority data: 07/853,607 18 March 1992 (18.03.92) US 08/031,391 12 March 1993 (12.03.93) US	(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
(71) Applicant: THE SPECTRANETICS CORPORATION [US/US]; 96 Talamine Court, Colorado Springs, CO 80907 (US).	Published <i>With international search report.</i> <i>With amended claims.</i>
(72) Inventors: HAMMERSMARK, Dan, J. ; 2030 Grosebear Lane, Colorado Springs, CO 80916 (US). WOOD, Timothy, J. ; 355 Jaycee Drive, San Luis Obispo, CA 93405 (US). SOLAR, Matthew, S. ; 115200 Buenos Aires, Cooper City, FL 33026 (US).	

(54) Title: FIBER OPTIC CATHETER WITH TWISTABLE TIP



(57) Abstract

The present invention is a catheter (10) with a twistable tip. The catheter having a flexible wall for use in complex twisting anatomy contains a torque wire (50) or a torqueable guide wire lumen (20). The torque wire or torqueable guide wire lumen extends through the length of the catheter and is attached to the catheter at or near the distal end thereof. The distal face of the catheter is angled to self align the catheter with an obstruction upon insertion. The proximal end of the torque wire protrudes from the proximal end of the catheter and is attached to a turn limiter (130). Rotation of the turn limiter imparts a torque to the torque wire or torqueable guide wire lumen which is transmitted through the catheter to the distal end of the catheter where the applied torque twists the distal tip to manually align the tip with an obstruction.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NL	Netherlands
BE	Belgium	GN	Guinea	NO	Norway
BF	Burkina Faso	GR	Greece	NZ	New Zealand
BG	Bulgaria	HU	Hungary	PL	Poland
BJ	Benin	IE	Ireland	PT	Portugal
BR	Brazil	IT	Italy	RO	Romania
CA	Canada	JP	Japan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SK	Slovak Republic
CI	Côte d'Ivoire	LJ	Liechtenstein	SN	Senegal
CM	Cameroon	LK	Sri Lanka	SU	Soviet Union
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	MC	Monaco	TG	Togo
DE	Germany	MC	Madagascar	UA	Ukraine
DK	Denmark	ML	Mali	US	United States of America
ES	Spain	MN	Mongolia	VN	Viet Nam

1

**FIBER OPTIC CATHETER
WITH TWISTABLE TIP**

BACKGROUND OF THE INVENTION

Field of the Invention

5 The present invention is directed to a fiber optic catheter, and more particularly to a fiber optic catheter with a twistable tip. The tip can be twisted remotely by rotating the proximal end of a torquing means internal to the catheter. The 10 torquing means may be a torque wire or a guide wire lumen attached to the catheter at or near the distal end.

Description of the Prior Art

15 Fiber optic catheter assemblies have increasingly been used for probing and clearing obstructions in various vessels such as arteries. The size of the vessel and the distance from the insertion point to the critical region in the vessel determine the characteristics of the catheter to be 20 used. For example, in some situations it is desirable to insert a very thin catheter a considerable distance into a vessel. The catheter must be quite flexible so that it may be steered considerable distances through winding vessel 25 passages.

30 Once the tip of the catheter reaches the critical point of the vessel passage, it is often desirable to have the tip oriented in a particular direction. It would be ideal if the tip self aligned with the obstruction, however often the tip must be further positioned to carry out an operation. The diameter of the optical fibers in fiber optic catheters is quite small and it is often necessary to continuously move and retarget the

optical beam emanating from the optical fibers to ablate a large obstruction. Because the optical fibers are not independently directable inside the catheter, the entire end of the catheter containing the mounted optical fiber must be moved. This problem is addressed by Wells US Patent No.

5 4,844,062. The Wells patent discloses an eccentric catheter having optical fibers located off the axial center of the catheter. When the catheter is
10 rotated, the beam from the optical fiber sweeps out a path larger than the diameter of the beam.

15 A catheter used to traverse considerable distances through a complex anatomy must be flexible. Commonly, the torque to rotate the tip is transmitted through the flexible outer jacket of the catheter. However, the torque applied at the proximal end of the catheter often will not be transferred to the distal end to rotate the tip. Instead the catheter will likely twist and kink
20 under the torsional load. The friction between the catheter and its surroundings over the length of the catheter in a complex anatomy is substantial and the flexible catheter does not have enough torsional rigidity to overcome the friction and transmit torque from its proximal end to its distal end.

25 One solution to this problem is to increase the stiffness of the catheter wall. This solution has the disadvantage of decreasing the steerability and the ease of insertion of the catheter into a winding passage. This solution is thus limited to short distance and direct insertions.

30 35 Flexible catheters do not have sufficient torsional stiffness to be twisted and rigid catheters do not have sufficient flexibility to be

inserted into a complex passage. Ideally a catheter should be flexible to permit adequate insertion and steerability while being able to transmit sufficient torque to twist the tip. Additionally the catheter should self align with the obstruction so that a minimum of remote intervention is required. The known art does not disclose any device to self align the tip of a catheter inserted in a complex anatomy. Clark et al. U.S. patent 5,114,403 discloses a catheter torque mechanism having a torque wire attached to the tip of a catheter and attached to a rotation control mechanism. Clark does not disclose attaching the torque wire to specific points near the catheter tip to achieve specific torque performance, nor does Clark teach altering the material or dimensions of the torque wire to achieve the torque and flexibility profile necessary to be effective in a complex anatomy.

Mueller, Jr., Patent No. 4,775,371 discloses a stiffened dilation catheter having a catheter with a section made from material being stiffer or having thicker proximal walls at a distal section of the catheter.

Sampson et al. US Patent Numbers 4,573,470 and 4,641,654 disclose steerable catheters having a rotatable guide wire. However, the guide wire does not impart any rotation or torque to the tip of the catheter. Gould et al. US Patent Number 5,055,109 and Gaiser et al. US Patent Number 4,998,917 disclose steerable catheters with torque transmitting assemblies. However, these inventions disclose deflecting the tip so that it is steerable, not twisting the tip.

A common feature required for most steerable catheters is a turning means at the

proximal end of the catheter. Common turning and turn limiting devices are disclosed by Frisbie et al. US Patent Numbers 4,664,113 and 4,619,263. These patents disclose screw and thread devices which impart an axial dislocation of a wire employed to steer a catheter.

SUMMARY OF THE INVENTION

The present invention addresses the above deficiencies by providing a catheter with a tip which may be remotely twisted by transmitting torque necessary to rotate the tip through a torque transmitting means extending inside the catheter and fixed to the catheter at or near the distal end, thus eliminating the need to rotate the entire catheter to align the tip. The torque transmitting means may be a torque wire or a torquable guide wire lumen. The torque wire or guide wire lumen protrudes from the catheter at the proximal end and can be fixed to a turn limiter for rotating the torque wire or guide wire lumen relative to the catheter and for preventing over-torquing of the torque transmitting means. All catheters disclosed and claimed herein may be operated with any of the turn limiters of the copending continuation-in-part application to Hammersmark et al., filed concurrently herewith, the subject matter of which is hereby incorporated by reference.

The torque transmitting means is attached to the catheter such that when the proximal end of the torque wire or lumen is turned, torque is applied to and twists only the distal end of the catheter. When a torque wire is used, the torque wire may be attached to the catheter by a number of techniques including attaching the wire to the

catheter itself or to optical fibers in the catheter near the distal face, attaching the wire to a torque ring near the distal face, attaching the wire to a fixed inner lumen at or near the distal face, and 5 employing a guide wire as a selectively attachable torque wire at the distal tip. Thus a flexible catheter can be inserted into a complex passage and the tip can be twisted without rotating the entire catheter and transmitting torque through its 10 flexible walls.

To aid in accurate positioning of the distal face relative to an obstruction and to aid in inserting the catheter through complex passages, the 15 tip of the present invention may have an angled distal face or a conical distal face. The angled face necessarily has a distal most edge which first contacts an obstruction and automatically turns the face to slide along the obstruction until the entire angled face contacts the obstruction. As a result, 20 the tip self aligns with the obstruction to provide a more efficient orientation for ablating the obstruction.

A conical face has a distal-most portion at the center of a cross section of the catheter. 25 The conical face ensures that the catheter remains centered in the vessel as it is inserted, and it resists becoming caught on obstructions.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other objects and advantages of this invention will become apparent and more readily appreciated from the following detailed description of the presently preferred exemplary embodiments of the invention in conjunction with the accompanying drawings, of which:

FIGURE 1 is an elevation, partially broken-out view of a fiber optic catheter with twistable tip according to an embodiment of the present invention;

FIGURE 2 is an end view of the distal end of the catheter shown in FIGURE 1;

FIGURE 3 is an elevation of a fiber optic catheter with twistable tip according to another embodiment of the present invention;

FIGURE 4 is a cross-sectional view of Section 4-4 of FIGURE 3;

FIGURE 5a is a schematic view of a third embodiment of the present invention;

FIGURE 5b is a schematic view of a fourth embodiment of the present invention;

FIGURE 6 is a schematic view of a fifth embodiment of the present invention;

FIGURE 7 is a perspective view of a fiber optic catheter with twistable tip according to yet another embodiment of the present invention;

FIGURES 8a-8f are schematic views of various fiber optic catheters with a twistable self aligning tip according to the present invention.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EXEMPLARY EMBODIMENTS

FIGURE 1 illustrates a catheter 10 made of conventional materials and containing an inner lumen

20. Inner lumen 20 contains a guide wire used to direct the catheter through the passages of a vessel. Inner lumen 20 is exposed at the distal end 90 of catheter 10. The remaining space inside 5 catheter 10 is filled with optical fibers 15 which are exposed at the distal tip 55.

10 Catheter 10 is also provided with a means to remotely twist the tip. This is accomplished by a torque wire 50 which extends through the catheter 10 and is attached at the distal tip 55.

15 A torque wire 50 extends from the proximal end 70 of the catheter 10 through the catheter to its attachment point near the distal end 90. Torque wire 50 is rigidly attached to the distal portion of the catheter such that torque of the torque wire is transmitted to and twists the distal tip. The 20 distal tip 55 of the catheter can be made of a radiopaque material such as metal to aid in viewing the position of the catheter.

25 As shown in FIGURES 1 AND 3, the torque wire 50 may have one or more tapers 51 near the distal end to increase the flexibility and steerability of the catheter and obtain the proper torsional stiffness of torque wire 50. For example, the torque wire 50 may be 0.018 inch in diameter 30 through the body of the catheter and may taper to 0.008 inch and further to 0.005 inch in diameter. The torque wire tip 25 can also be flattened to provide a larger surface for bonding to the distal end of the catheter.

35 The distal end of the torque wire may be attached directly to the catheter wall, or to the inner lumen 20, as shown in FIGURE 5a. The point of attachment 21 may be at the distal tip, FIGURE 5a, or at a distance back from the distal tip, as shown

in FIGURE 5b. The location of the point of attachment 21 is determined by the flexibility and torque response characteristics desired. Although the torque wire may be attached to the inner lumen up to 30 cm from the distal face, the ideal attachment position is approximately 3-10 cm from the distal face. A significant advantage of attaching the torque wire to the inner lumen at a position back from the distal tip is that the portion of the catheter beyond the attachment point can be made more flexible for passing through complex passages. Also, this embodiment can provide better torque response at the tip because, depending upon the materials chosen, the inner lumen can transmit the torque to the tip better than a small diameter torque wire.

Alternatively, the torque wire is attached to the tip of the catheter by bonding the distal end with the optical fibers 15 in an adhesive matrix, as shown in FIGURES 1 and 2. The torque wire may also be attached to a torque ring which is fixed in the catheter near the distal end. See FIGURES 3 and 4. The torque ring 30 is attached to the catheter so that a torque applied to the torque ring is transmitted to the catheter 10. Torque wire 50 of this embodiment has at least one taper 51 near the distal end, to increase the steerability of the catheter. In fact, torque wire 50 can have the same tapered form as described above. The torque wire is attached to the torque ring by an adhesive bond or weld 40 or other common attaching means. The torque ring may be of any material having sufficient strength and can be made radiopaque to aid in positioning the distal tip 90 of the catheter.

Another technique for rotating the distal end of the catheter is by a key and slot mechanism, shown in FIGURE 7. In this embodiment, the guide wire is transformed into a torque wire by sliding a 5 key shaped block 55 into a keyed receiving slot 45 of the inner lumen. The key 55 is rigidly attached to guide/torque wire 35 so that rotating guide/torque wire 35 necessarily rotates key 55. When the tip of the catheter is properly positioned 10 in the vessel, guide/torque wire 35 is retracted into lumen 20. Key 55 is drawn into and rotatably locked to slot 45. If the guide/torque wire 35 is now rotated, torque is applied through the key and slot to twist the distal tip of the catheter. The 15 key shaped block may alternatively be an adhesive, solder, or other material applied to the guide wire and formed into a non-round shape corresponding to any non-round shape of the inner lumen. The guide/torque wire of this embodiment may taper one 20 or more times near the distal end to increase steerability of the catheter. The key and slot alternative of attaching the torque wire to the distal end of the catheter is particularly 25 advantageous because it results in a more flexible catheter. By combining the functions of both the torque wire and guide wire into one wire, interior space is preserved and a reduction of the complexity and cost of the catheter is achieved.

Another embodiment of the invention shown 30 in FIGURE 6 combines the function of a guide wire lumen and the function of the torque wire. In this embodiment, a guide wire lumen 120 replaces the torque wire of the previous embodiments and provides torque to the distal end. The guide wire lumen 120 35 is attached to the catheter wall 105 at or near the

distal end of the catheter but is otherwise not fixed to the interior of the catheter. The guide wire lumen extends over substantially the length of the catheter and may have a number of discrete 5 sections 110, 111, 112 composed of different materials so as to achieve the desired torque response and flexibility. For example, a torquable inner lumen may have three sections: a distal tip section 110 of standard inner lumen material 10 connected to a section of reinforced lumen 111 followed by a proximal section of hypotube 112 which extends to the proximal end of the catheter.

The distal section 110 may be unreinforced to provide increased flexibility. The standard inner 15 lumen material may be polyethylene, polyester, teflon, polyamide, etc. The reinforced section 111 may comprise a lumen with a coil or braid of reinforcing material encapsulated within the standard inner lumen material. The reinforcing 20 material may be stainless steel or Kevlar. The proximal section 112 may be NiTi or Stainless Steel hypotube to provide efficient torque response through most of the length of the catheter, while allowing a guide wire to pass therethrough. Because 25 of the stiffness of the hypotube, the proximal section does not extend to the distal end of the catheter but connects with the reinforced section about 25cm from the distal end. The distal-most portion and the reinforced portion together extend 30 the remaining distance to the distal tip of the catheter 10. The lengths and number of sections may be varied to achieve the desired torque response and flexibility profile at the tip. The torquable guide wire lumen, therefore, may have more or fewer

material transitions, depending upon the desired torque characteristics of the catheter.

The advantage of the torquable guide wire lumen over the torque wire are numerous. The 5 catheter can be built with one less element, the torque wire, thus freeing up space and improving the flexibility of the catheter. A catheter with a torquable guide wire lumen can provide better torque response than a catheter with a torque wire. Also, 10 using a torquable guide wire lumen allows for a straight exit path for the torque and guide wire element at the proximal end of the catheter system. Normally, the torque wire and the guide wire lumen would have different exit paths at the turn limiter, 15 thus, one of the elements would have a curved exit path. Catheter 10 terminates at a torque knob assembly 130 having a hollow axle 113 extending therethrough. The guide wire lumen communicates with the hollow axle thus providing a guide wire 20 insertion point 140 for the catheter.

When inserting a catheter into a vessel, it is desirable to have the catheter self align to the extent possible with the obstruction. One feature of the present invention provides a self 25 aligning twistable tip. See FIGURES 8a-8f. The catheter 10 comprises an inner lumen 20 and is packed with optical fibers 15. The fibers terminate at the distal face which is angled. The face is made at an angle α relative to a perpendicular to 30 the axis of the catheter which is greater than 0 degrees and preferably about 23° , such that when the catheter 10 is advanced into the vessel over a guide wire passing through lumen 20, the distal most point 35 of the face contacts the obstruction and twists the face and tip to slide over the obstruction until all

or most of the angled face contacts the obstruction. This twistable tip with angled face is applicable to catheters having concentric (FIGURES 8e and 8f), or eccentric (FIGURES 8a-8d) guide wires and whether 5 the guide wires extend the length of the catheter (FIGURES 8d and 8e) or are of the monorail variety (FIGURES 8c and 8f). Catheter 10 may be any of the catheters in FIGURES 8a-8f, this means that any of the twistable catheters previously discussed may 10 have an angled face.

Additionally, an angled catheter tip face facilitates insertion of the catheter through a passage. While a catheter with a flat distal face perpendicular to the axis of the catheter may be 15 impeded by obstacles which contact the flat face near the edges, an angled face will deflect off obstructions and continue through the passage.

Referring to FIGURE 6, such an angled catheter tip is ideally shaped conically 106. Such 20 conical face may be concentric with the axis of the catheter as shown, or it may be eccentric such that the tip is offset from the center of the catheter. A conical shape rather than a single angled face provides a deflecting surface in all directions. 25 The conical surface 106 of the present invention makes an angle α of about 23° with a plane perpendicular to the axis of the catheter. Greater angles may cause total internal reflection of optical energy exiting through the fiber faces. An 30 angled tip catheter of this sort may be either eccentric or concentric with respect to an inner lumen. A conical face, centered either on the longitudinal axis of the catheter or the longitudinal axis of the guide wire lumen, or 35 eccentric relative to both the catheter and the

lumen may be used with any of the catheters 10, described above.

The torque wire 50, guide/torque wire 35, or torquable inner lumen (referred to hereinafter 5 collectively as a torque element) of the present invention is composed of any suitable material of sufficient lateral flexibility but strong torsional rigidity. The torque element is attached to the catheter at only one attachment point. In all other 10 locations, the torque element rotates freely inside the catheter. It is not necessary that the axis of the torque element and the axis of the catheter be the same at the attachment point. A torque element attached to the catheter off of the catheter axis 15 will provide twisting motion of the tip, not around the axis of the torque wire.

At the proximal end of the catheter, the torque element protrudes from the catheter and is attached to a turn limiter. A turn limiter refers 20 to any of the devices in the copending continuation-in-part application filed concurrently herewith. A turn limiter provides a means to rotate the torque element to provide torque to the distal end, and also a means to limit the torque applied to the 25 torque element to prevent damage to the catheter system. When the torque element is rotated at the proximal end of the catheter 10, torque is transmitted through the catheter to the attachment point where the torque is applied to the catheter 30 thus twisting the tip.

The amount of twist of the catheter tip is determined by the amount of rotation of the torque element applied at the proximal end, the flexibility of the catheter wall and the rigidity of the torque 35 element. Ideally, the distal section of the

catheter is more flexible than the remainder of the catheter. The flexibility of the distal section of the catheter can be increased by replacing a distal section of the normal catheter wall with a more 5 flexible catheter material, or by changing the wall thickness of the outer lumen near the distal end, or a combination of differing materials and differing wall thickness. A flexible distal section of the catheter improves the trackability of the catheter 10 upon insertion into a vessel and also improves the twistability of the distal tip. Ideally, a distal section of about 4-30cm may be provided with a flexibility feature as described above.

If too much torque is applied to the 15 torque wire, damage may occur to a number of components of the catheter. The flexible walls of the distal end of the catheter, the optical fibers, the torque element, and also the surrounding vessel are all susceptible to damage from over-torquing the 20 torque element. Thus, a turn limiting device is connected to the proximal end of the torque element which limits the number of rotations that may be applied to the torque element relative to the catheter.

25 Although only a few embodiments of this invention have been described in detail above, those skilled in the art will readily appreciate that many modifications and combinations are possible without materially departing from the novel teachings of 30 this invention. Accordingly all such modifications are intended to be included within the scope of this invention.

WHAT IS CLAIMED IS:

1. A catheter assembly with a twistable tip comprising:

5 a catheter having a distal end;
a plurality of optical fibers
disposed in the catheter and having distal ends
extending to the distal end of the catheter; and
a torque wire extending through the
catheter and bonded to at least one of the catheter
10 and the optical fibers near the distal end;
such that when a proximal end of the
torque wire is rotated, torque is transferred
through the torque wire to the distal end of the
catheter thus twisting the tip of the catheter.

15 2. A catheter assembly with a twistable tip comprising:

a catheter;
a torque ring fixed relative to an
inner surface of the catheter near the distal end of
20 the catheter; and
a tapered torque wire fixedly
attached to the torque ring, such that any torque
applied to the torque wire is imparted to the
catheter by the torque ring.

25 3. A catheter assembly with twistable tip comprising:

a catheter having a distal end;
an inner lumen extending from the
distal end to a proximal end within the catheter;
30 a torque wire extending through the
catheter and bonded to at least one of the catheter

wall and the inner lumen at a point back from the distal end;

5 such that when a proximal end of the torque wire is rotated, torque is transferred through the torque wire to the inner lumen and subsequently to the distal end of the catheter.

10 4. The catheter assembly with a twistable tip as in claim 1, 2 or 3, wherein the torque wire has at least one tapered portion near the distal end of the catheter.

15 5. A catheter assembly with twistable tip comprising:

15 a catheter having a distal end; and an eccentric inner guide wire lumen extending from the distal end to a proximal end within the catheter, the inner lumen being attached to the catheter at the distal end,

20 the inner guide wire lumen having a structure to transmit torque such that when a proximal end of the inner lumen is rotated, torque is transferred through the inner lumen to the distal end of the catheter.

25 6. A catheter assembly with twistable tip according to claim 5, further comprising a means for rotating the guide wire lumen attached to the proximal end of the catheter such that a proximal end of the guide wire lumen protrudes from a distal portion of the rotating means.

30 7. A catheter assembly with twistable tip according to claim 6, wherein the protruding

proximal end of the guide wire lumen is an insertion point for a guide wire.

8. The catheter assembly with a
twistable tip as in claim 1, 2, 3 or 5, wherein a
5 distal face of the catheter is not perpendicular to
a longitudinal axis of the catheter.

9. The catheter assembly with a
twistable tip as in claim 8 wherein the catheter
includes an eccentric guide wire lumen and the
10 distal face is angled such that the eccentric guide
wire lumen is exposed at a distal-most portion of
the distal face.

10. The catheter assembly with a
twistable tip as in claim 1, 2, 3 or 5, wherein a
15 distal face of the catheter is a cone.

11. A catheter assembly with twistable
tip according to claim 1, 2, 3 or 5, wherein the
inner lumen includes a plurality of material
transition points along a length of the inner lumen
20 defining a plurality of longitudinal sections.

12. A catheter assembly with twistable
tip according to claim 11, wherein one longitudinal
section has a thinner wall cross section than an
adjacent section.

25 13. A catheter assembly with twistable
tip according to claim 1, 2, 3 or 5, wherein a first
longitudinal section of the inner lumen is composed
of a different material than a second adjacent
longitudinal section of the inner lumen.

14. A catheter assembly comprising:
a catheter having a distal face; and
a plurality of optical fibers disposed in
the catheter and extending to the distal face,

5 the distal face forming a non-zero angle
with a plane perpendicular to a longitudinal axis of
the catheter.

10 15. The catheter assembly as in claim 14
wherein the catheter includes an eccentric guide
wire lumen, the distal face being formed such that
said eccentric guide wire lumen is exposed at a
distal-most portion of the distal face.

15 16. The catheter assembly as in claim 14
wherein the catheter includes a guide wire lumen
concentric with the catheter at the distal face.

17. The catheter assembly with a
twistable tip of claim 1, 2, 3, 5 or 14, wherein a
distal section of the catheter is more flexible than
a remainder of the catheter.

20 18. The catheter assembly with twistable
tip as in claim 1, 2, 3, 5 or 14, wherein the
catheter includes a guide wire lumen concentric with
the catheter at the distal face.

AMENDED CLAIMS

[received by the International Bureau on 24 August 1993 (24.08.93);
original claims 14-18 amended; other claims unchanged (1 page)]

14. A flexible catheter assembly comprising:
a flexible catheter having a distal face; and
a plurality of optical fibers disposed in the
catheter and extending to the distal face,
the distal face forming a non-zero angle with a
plane perpendicular to a longitudinal axis of the catheter.
15. The flexible catheter assembly as in claim 14,
wherein the catheter includes an eccentric guide wire lumen,
the distal face being formed such that said eccentric guide
wire lumen is exposed at a distal-most portion of the distal
face.
16. The flexible catheter assembly as in claim 14,
wherein the catheter includes a guide wire lumen concentric
with the catheter at the distal face.
17. The flexible catheter assembly with a twistable
tip of claim 1, 2, 3, 5, or 14, wherein a distal section of
the catheter is more flexible than a remainder of the
catheter.
18. The flexible catheter assembly with a twistable
tip of claim 1, 2, 3, 5, or 14, wherein the catheter includes
a guide wire lumen concentric with the catheter at the distal
face.

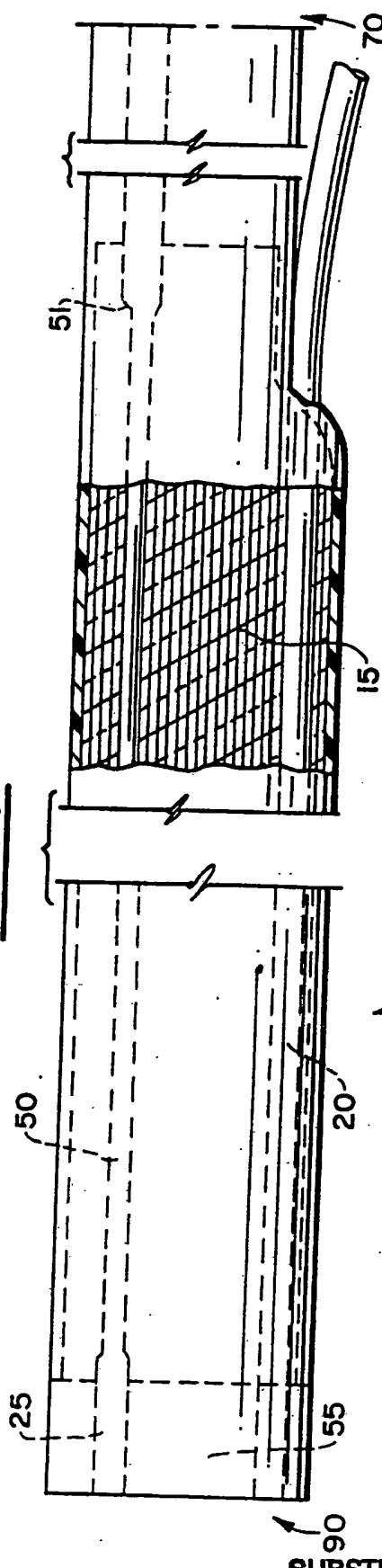
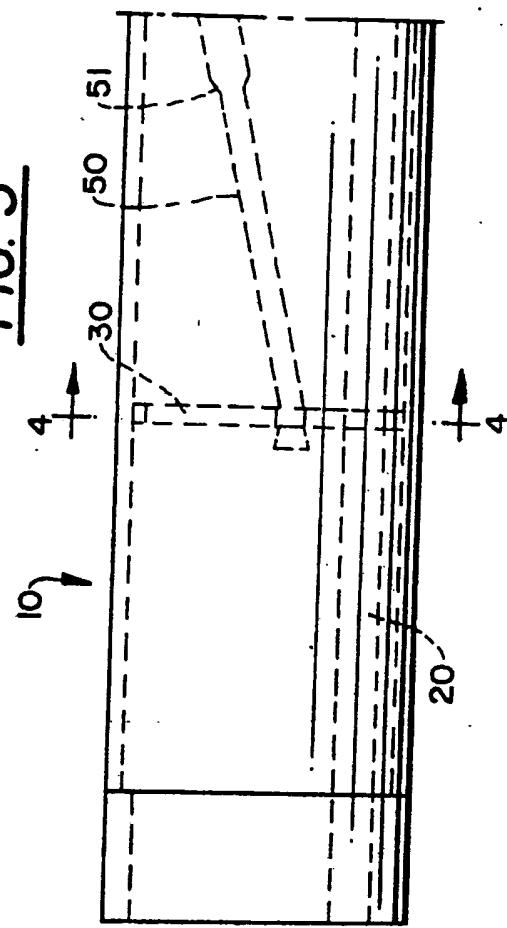
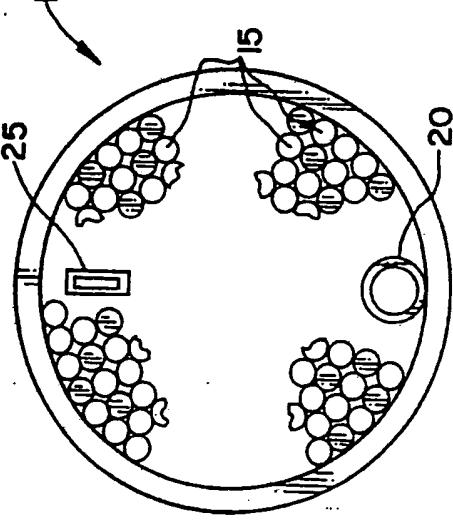
FIG. 1FIG. 3FIG. 2

FIG. 7

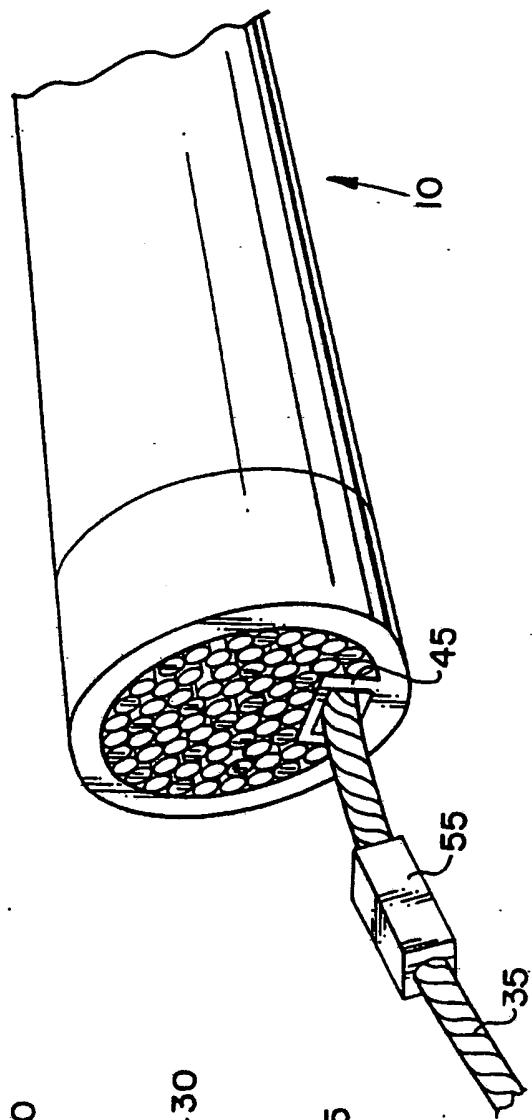


FIG. 4

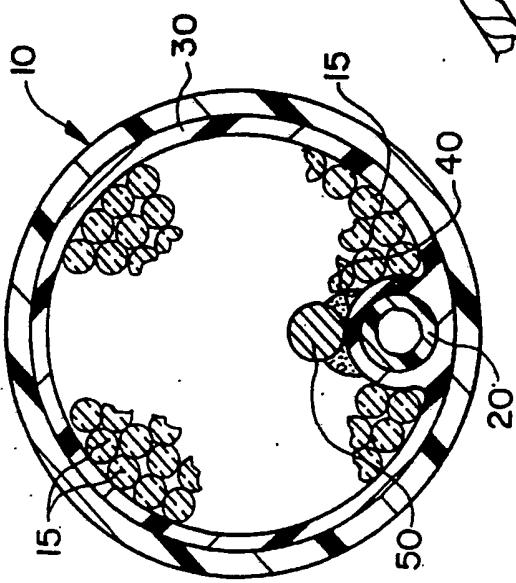
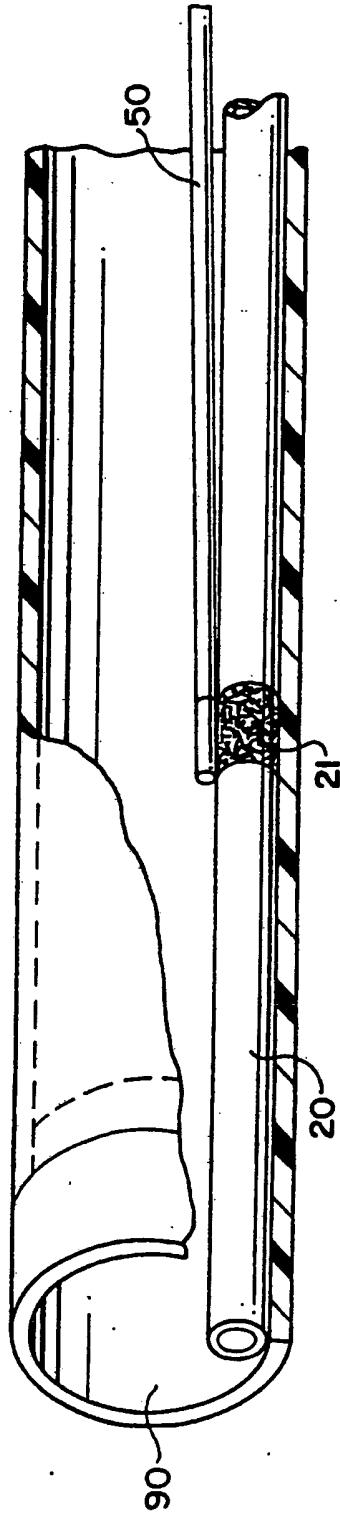
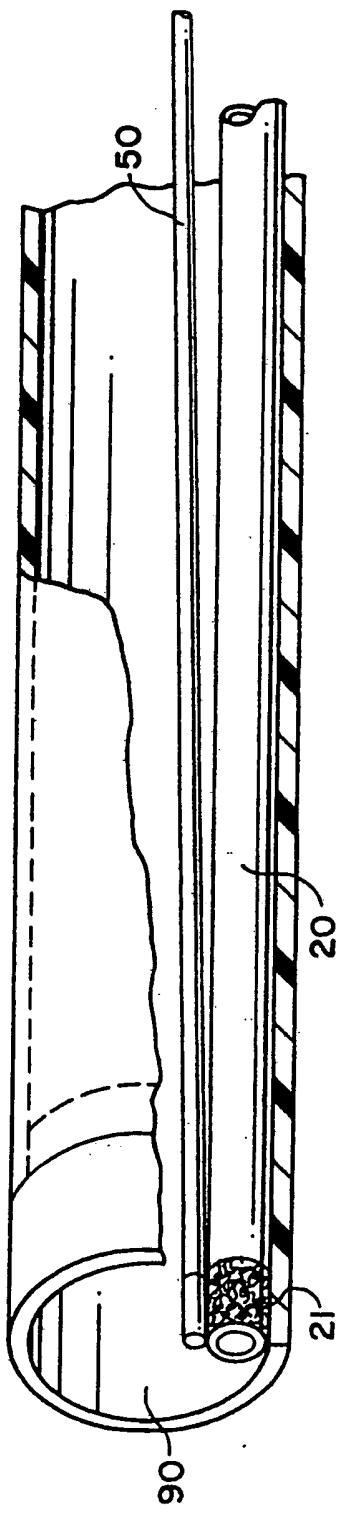
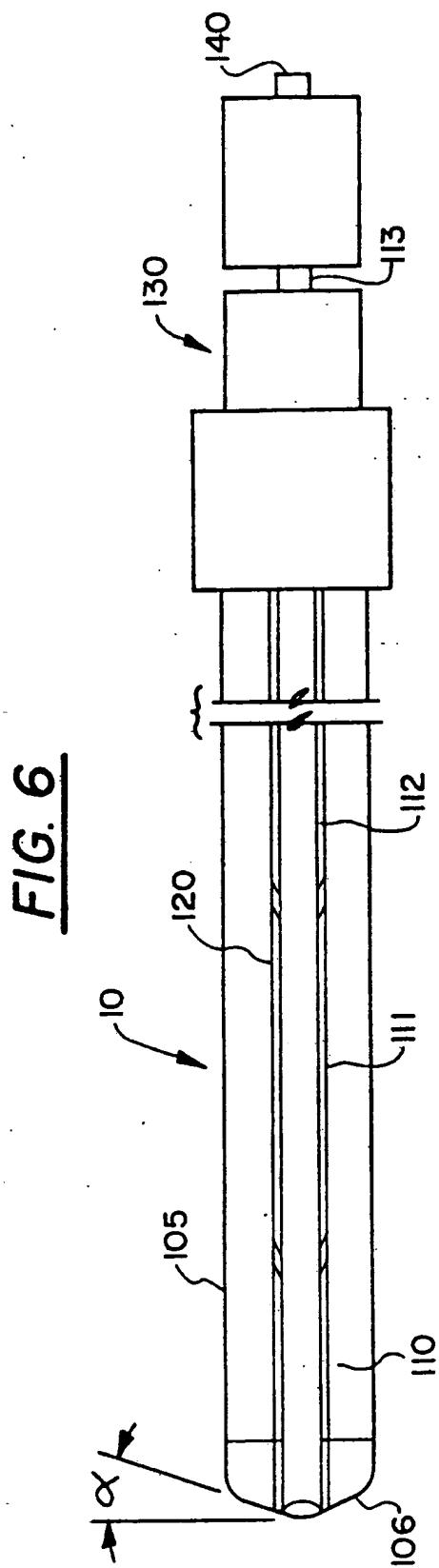
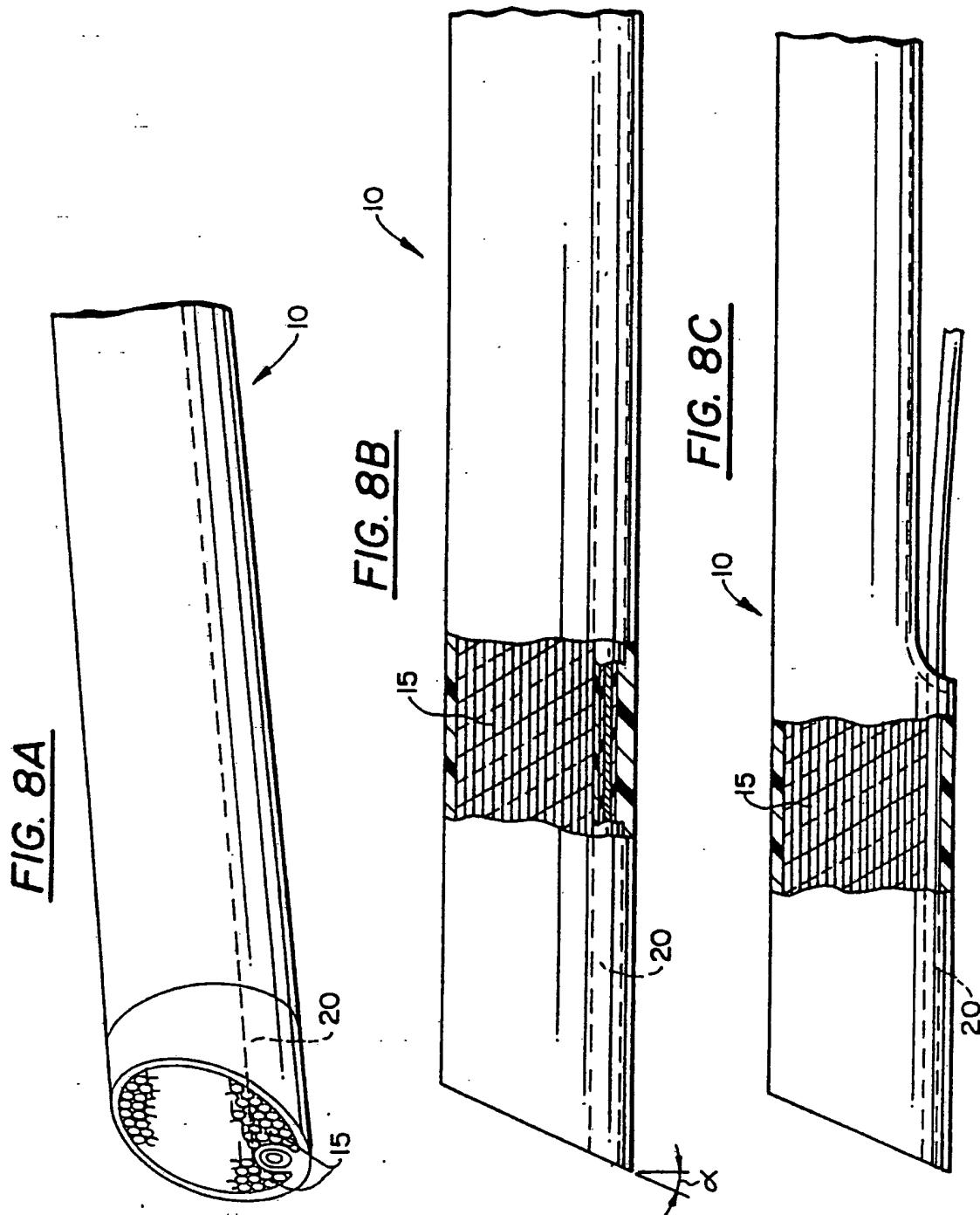
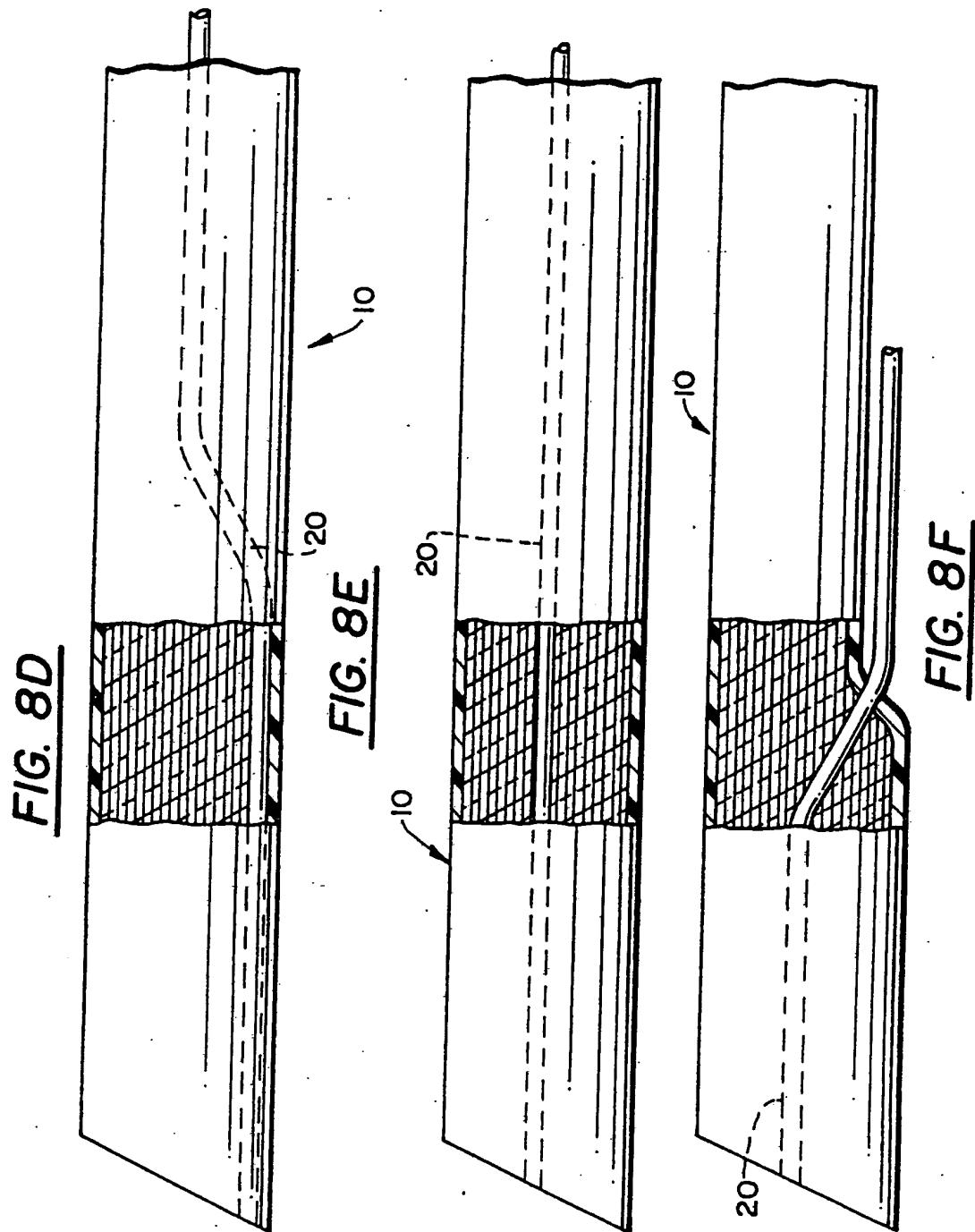


FIG. 5AFIG. 5B







INTERNATIONAL SEARCH REPORT

International application No.

PCT/US93/02225

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61M 37/00

US CL :604/95

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/96; 128/4,6,7, 657,722

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
noneElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
none

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P Y,P	US,A, 5,114,403 (Clarke et al.) 19 May 1992 (See Fig.; col. 3, lines 13-15).	<u>1-7,10,13,17</u> 8
X,P Y,P	US,A, 5,167,220 (Brown) 01 December 1992 (See Fig. 2; col. 4, lines 10-20).	<u>14</u> 8
A	US,A, 4,664,113 (Frisbie et al.) 12 May 1987.	1-18

Further documents are listed in the continuation of Box C. See patent family annex.

Special categories of cited documents:	
"A"	document defining the general state of the art which is not considered to be part of particular relevance
"E"	earlier document published on or after the international filing date
"L"	document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reasons (as specified)
"O"	document referring to an oral disclosure, use, exhibition or other means
"P"	document published prior to the international filing date but later than the priority date claimed
"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&"	document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 MAY 1993	21 JUN 1993

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer Mr. ADAM J. CERMAK MNGUYEN NGOC-HO INTERNATIONAL DIVISION
Facsimile No. NOT APPLICABLE	Telephone No. (703) 308-2110